

10/553595

JC12 Rec'd PCT/PTC 19 OCT 2005

PATENT

Customer No. 22,852

Attorney Docket No. 07680.0023-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|-----------------------------------|---|------------------------------------|
| In re Application of: |) | |
| |) | |
| LEDBETTER et al. |) | Group Art Unit: Not Yet Assigned |
| |) | |
| Application No.: Not Yet Assigned |) | Examiner: Not Yet Assigned |
| |) | |
| Filed: Herewith |) | |
| |) | |
| For: TGF-BETA ANTAGONISTS |) | Confirmation No.: Not Yet Assigned |
| COMBINED WITH RENIN- |) | |
| ANGIOTENSIN-ALDOSTERON- |) | |
| SYSTEM ANTAGONISTS FOR |) | |
| TREATING RENAL INSUFFICIENCY |) | |

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents on the attached listing. This Information Disclosure Statement is being filed within three months of the date of entry of the national stage in an international application and before the mailing date of a first Office Action on the merits for the above-referenced application.

Copies of the listed foreign and non-patent literature documents are enclosed.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.


Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: October 19, 2005

By: 

Leslie A. McDonell

Reg. No. 34,872

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| IDS Form PTO/SB/08: Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | Complete if Known 10/553595 | | |
| | | | Application Number | Not Yet Assigned | |
| | | | Filing Date | Herewith (October 28, 2005) | |
| | | | First Named Inventor | Steven Ledbetter et al. | |
| | | | Art Unit | Not Yet Assigned | |
| | | | Examiner Name | Not Yet Assigned | |
| Sheet | 1 | of | 1 | Attorney Docket Number | 07680.0023-00000 |

| U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS | | | | | |
|---|-----------------------|---|---|---|---|
| Examiner Initials | Cite No. ¹ | Document Number Number-Kind Code ² (if known) | Issue or Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | | | | |
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Note: Submission of copies of U.S. Patents and published U.S. Patent Applications is not required.

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|-----------------------|--|--------------------------------|---|---|--------------------------|
| Examiner Initials | Cite No. ¹ | Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | Translation ⁶ |
| | | WO 00/66631 | 9 Nov 2000 | Cambridge Antibody Technology Limited | | |
| | | WO 01/66140 A1 | 13 Sept 2001 | Genzyme Corporation | | |
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| NON PATENT LITERATURE DOCUMENTS | | | |
|---------------------------------|-----------------------|---|--------------------------|
| Examiner Initials | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | Translation ⁶ |
| | | Benigni et al., "Add-On Anti-TGF- β Antibody to ACE Inhibitor Arrests Progressive Diabetic Nephropathy in the Rat," <i>J. Am. Soc. Nephrol.</i> , 14:1816-1824 (2003) | |
| | | Chen et al., "Reversibility of Established Diabetic Glomerulopathy by Anti-TGF- β Antibodies in <i>db/db</i> Mice," <i>BBRC</i> , 300:16-22 (2003) | |
| | | Gaedeke et al., "Angiotensin II and Progressive Renal Insufficiency," <i>Current Hypertension Reports</i> , 4:403-407 (2002) | |
| | | Ling et al., "Therapeutic Role of TGF- β -Neutralizing Antibody in Mouse Cyclosporin a Nephropathy: Morphologic Improvement Associated with Functional Preservation," <i>J. Am. Soc. Nephrol.</i> , 14:377-388 (2003) | |
| | | Zoja et al., "How to Fully Protect the Kidney in a Severe Model of Progressive Nephropathy: A Multidrug Approach," <i>J. Am. Soc. Nephrol.</i> , 13:2898-2908 (2002) | |

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|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.